

## **PharmChem, Inc.**

PharmChek® Drugs of Abuse  
Patch



Presented by

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### **PharmChek® Drugs of Abuse Patch**



### **PharmChek® Drugs of Abuse Patch**

#### **Overview**

- Sweat Collection Issues
- What is PharmChek®
- How the Sweat Patch works
- Who is using PharmChek®
- Testing Methods and Cut off Levels
- Understanding PharmChek Results
- Application Instructions
- Removing Instructions
- Additional Information

## History of Drug Detection in Sweat

- Drugs known to appear in sweat:
  - methadone (1973)
  - PCP
  - amphetamines
  - nicotine
  - morphine
  - cocaine
  - phenobarbital

## History of Drug Detection in Sweat

- capillary micropipettes
- "dripping"
- filter paper swab
- plastic bag over arm
- rubber gloves
- cotton body suit
- plastic body bag
- whole body washdown
- occlusive sweat patch
- sweat patch (PharmChek®) non-occlusive

## PharmChek®Drugs of Abuse Patch

- The sweat patch is a non-occlusive, hypoallergenic collection device.
- The sweat patch was cleared as a collection device by FDA on October 4, 1990.
- The FDA cleared the sweat patch for the detection of cocaine, opiates and methamphetamine in 1995; for marijuana and phencyclidine in 1996.

## **PharmChek®Drugs of Abuse Patch**

### How the sweat patch works

- There are two means by which the body produces sweat
  - Insensible perspiration
    - the passive uncontrolled loss of sweat from the skin
  - Sensible sweat
    - the active controlled loss from specific glands in the skin

## PharmChek®Drugs of Abuse Patch

### How the Sweat Patch works

- The insensible perspiration is captured by the absorbent pad in the patch and analyzed for drugs.
  - approximately 300-700 ml of insensible sweat is excreted each day.
  - Approximately 2ml is absorbed in the patch each week.
- The absorbent pad is tested for the presence of drugs of abuse.

## **PharmChek®Drugs of Abuse Patch**

### How the sweat patch works

- The transparent film portion of the patch is a semi-permeable membrane that allows oxygen, carbon dioxide and water vapor to pass through the patch leaving the skin underneath health and sterile.
- Substances of large molecular weight are trapped in the absorbent pad portion of the patch.
- Non-volatile substances from the environment cannot penetrate the transparent film from the outside.

The diagram illustrates the PharmChek patch with the following components labeled:

- Polyurethane Film (outer layer)
- Absorption Pad (inner layer)
- Unique Number (small code)
- Release Liner (protective layer)

Below the diagram, a text box provides a description of the patch:

**PharmChek is a Sweat patch, worn on the skin surface, that acts as a specimen container for the non-volatile and liquid components of sweat.**

# PharmChek®Drugs of Abuse Patch

## Understanding Sweat Patch Results

**Detection Periods in sweat differ from those in urine, the sweat patch is a collection device designed to retain evidence of drug use.**

- Results cannot be used to:
  - reflect the dose of drugs taken.
  - reflect the time of use.
  - determine if multiple small doses or one large dose of drug is ingested.
  - show when drug use occurred.

## PharmChek®Drugs of Abuse Patch

## PharmChek®Drugs of Abuse Patch

### ■ Active Research Programs

- Addiction Research Center
- Center for Human Toxicology
- NIDA
- Armed Forces Institute of Pathology
- Researches in Drug Metabolism

## PharmChek®Drugs of Abuse Patch

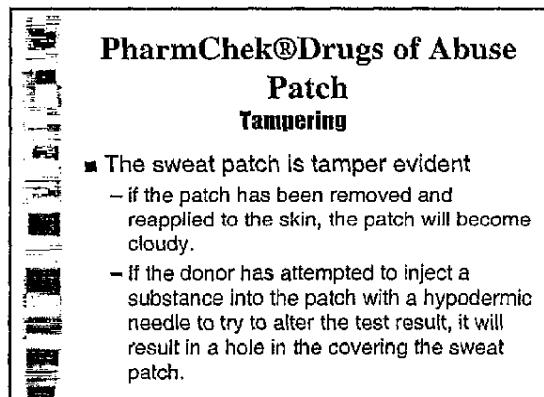
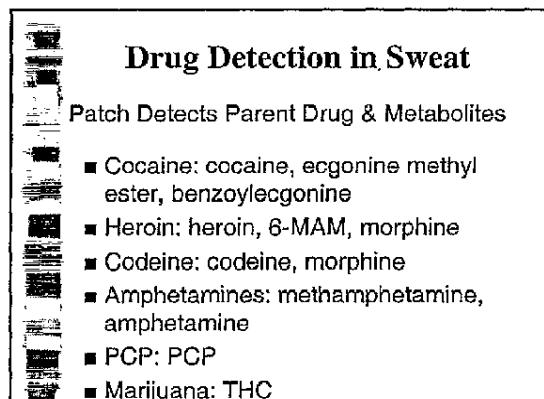
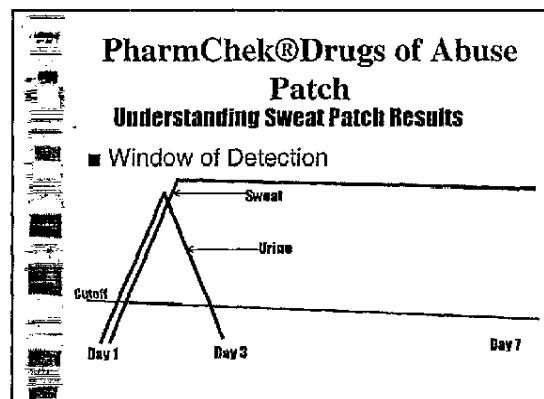
### Testing Methods & Cutoff levels

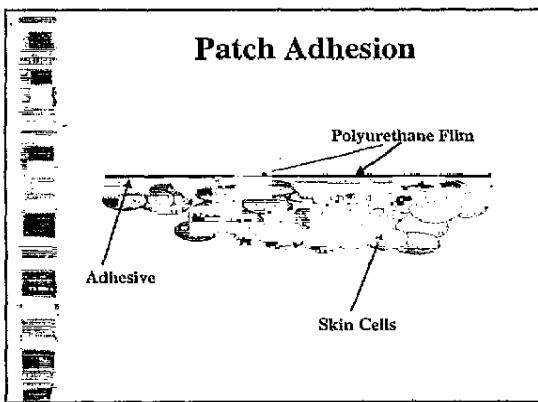
Drug or Drug Class Analyte	Patch Screening	Drug or Drug Class Analyte	Patch Confirmation GC/MS
Cocaine	EA 10 ng/ml	Cocaine Benzoylecdonine	10 ng/ml 10 ng/ml
Opiates	EA 10 ng/ml	Heroin 6-MAM Morphine Codeine	10 ng/ml 10 ng/ml 10 ng/ml 10 ng/ml
Amitriptylines	EA 10 ng/ml	Amitriptylines Methamphetamines	10 ng/ml 10 ng/ml
Marijuana	EA 1.5 ng/ml	Marijuana	5 ng/ml
Phencyclidine	EA 7.5 ng/ml	Phencyclidine	7.5 ng/ml

## PharmChek®Drugs of Abuse Patch

### Understanding Sweat Patch Results

- A positive result indicates drug use occurred during the time the patch was worn or 24-48 hours before the patch application.





### PharmChek®Drugs of Abuse Patch

#### Wear Time

- Patches must be worn for a minimum of 24 hours.
- Sweat patches can be worn for up to 7 days
  - if the patch is worn longer than 7 days, the test will be valid as long as there is a clear seal around the pad.

### PharmChek®Drugs of Abuse Patch

#### Inadvertent exposure

- The following will not effect the results of the test:
  - Outside contaminants
    - Marijuana smoke filled rooms will not effect the test results
- Contact with persons using drugs
  - Kissing, hugging, sexual activity etc... Will not effect the test.
- "Flushing"
  - drinking a lot of water after taking drugs will not keep the donor from having a positive test.

## Drug Detection in Sweat - PharmChek®

### Large-scale Field Use Evaluation

- Parallel testing with urine and PharmChek®
- Urine and PharmChek® result correlated
- 1,054 subjects
- 2,885 PharmChek® and 10,080 urine specimens

## PharmChek®Drugs of Abuse Patch

### Advantages of PharmChek®

- The distinct advantages:
  - Increased window of detection
  - Acts as a deterrent to drug abuse
  - Detects Parent Drug and Metabolites
  - Variable Removal Date
  - Quick Application and Removal
  - No urine collections
  - No Sample Substitution
  - No Sample Dilution

## PharmChek®Drugs of Abuse Patch

### ■ Training Programs

- Complete training programs up to and including a collector certification program are in place.

## PharmChek®Drugs of Abuse Patch

### Application of PharmChek®

#### ■ Applying the Patch

- Remove patch from envelope.
- Remove backing (only the white backing with PharmChek logo).
- Be sure the number on the patch is right side up.
- Apply the patch onto the cleaned area of the skin.
- gently rub the area of film around the absorption pad.
- Remove the border and gently rub outside edge of the patch.

## PharmChek®Drugs of Abuse Patch

### Recommended areas to wear the Patch

#### ■ Select Area to apply the patch

- Upper or outer arm
- Lower midriff
- Lower back

#### ■ Cleaning Application Area

- Aggressively Clean application area (8" x 8") using the alcohol swabs provided.
- Let area Dry 60-90 seconds

### Clean Skin With Alcohol Wipe



**Place Patch Over Skin**



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**Rub Around Absorbent Pad**



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**Remove Patch "Window Frame"**



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### Rub Around Edge Of Patch



### PharmChek®Drugs of Abuse Patch

#### Application Tips & Questions

- Have the donor flex his/her arm before applying the patch.
- The patch should not be placed on skin that has scratches, lesions, or excessive hair.
- The patch can be placed over a tattoo if no other areas are available
  - choose the lightest part of the tattoo to apply the patch.

### PharmChek®Drugs of Abuse Patch

#### Chain of Custody

Complete the application section of the Chain of Custody form:

– Donor ID Number	– Patch number
– Donor's name (optional)	– Date
– Treatment Status/Reason	– Observer's Initials
• Random, Probable Cause, Retest, In Treatment, Medical, Other.	– Donor's Initials

Let the donor know when he/she is to return to have the patch removed.

## **PharmChek®Drugs of Abuse Patch**

## **Donor Instructions**

- The donor should be told that if the patch appears to be coming loose, it is his/her responsibility to tell a staff person prior to the patch removal date.
- If the patch is removed early, another patch may be applied to the donor.
- The donor may perform normal activities such as work, bathing, showering and exercising, etc.

## PharmChek®Drugs of Abuse Patch

## **Removal Instructions**

- Supplies necessary for Removal of PharmChek®
  - Chain of Custody Form
    - The form used when applying the patch.
  - Specimen Bag
  - Disposable Plastic Tweezers and Plastic Gloves
  - Transport Bag

## PharmChek®Drugs of Abuse Patch

## Removal Tips

- Look for puncture holes
  - \* For best results, hold patch up to the light after removal.
- Request that the donor pull down the top edge of the patch
  - using the gloved hand, pull the patch half way down
  - using the single-use tweezers, remove the cellulose pad and place the pad in the specimen bag.
  - Affix a bar-code sticker, from the chain-of-custody form, to the outside of the specimen bag.

**Donor Peels Outer Cover  
Of Patch Down**



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**PharmChek®Drugs of Abuse  
Patch**

**Observation after Removal**

- **Confirm patch Number**
  - Compare the number on the patch with the number on the Chain of custody form.
  - The observer must initial the boxes marked "Observer's Initials".
- **Examine Patch for Tampering**
  - Look for signs of attempts to remove and re-apply
    - An uncompromised patch should have the adhesive still adhering to the skin completely surrounding the absorption pad.

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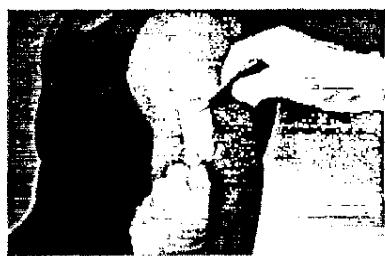
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**Remove Absorbent Pad**



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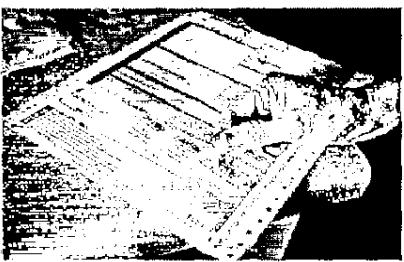
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### Remove Barcode Label



### PharmChek®Drugs of Abuse Patch Removal Information

#### Complete Chain of Custody

##### Removal

Date removed

Observer's Initials

Donor's initials

##### Use Information

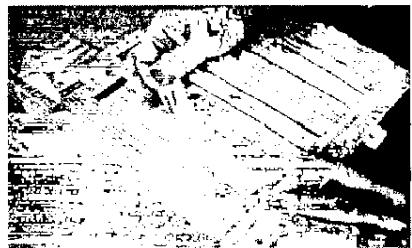
Indicate whether the patch fell off or was taken off.  
If the patch was removed before the wear period was completed, indicate the reason.

If Patch appears to have been tampered with, check the "Yes" box and indicate how.

### Place Absorbent Pad In Bag



### Peel Off Security Seal



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### PharmChek®Drugs of Abuse Patch

#### Removal Instructions

- Comments
- Medication used
- Donor signature
- Observers signature
- place the plastic specimen bag into the transport bag with the chain-of-custody form.
- Place the transport bag into the appropriate shipping envelope and send to PharmChem Laboratories for testing.

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### Place Barcode Label On Bag



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## **PATCH COURT CASES UPHELD**

- There have been a number of cases at the Federal and local levels challenging The Sweat Patch .
- In 3 cases in the State of CA the Patch has undergone a challenge under the Kelly Statute and one Federal challenge under the Daubert Statute which generally asks :
- Is this a new Technology ?
- Is this Technology accepted by the scientific community ?

## **PharmChek®Drugs of Abuse Patch**



END